



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/881,509	06/24/97	SCHENDEL	D P564-7015

HM12/0320
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EXAMINER

DECLoux, A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 03/20/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/881,509

Applicant(s)

Schendel

Examiner

DeCloux, Amy

Group Art Unit

1644

- ☐ Responsive to communication(s) filed on _____.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 1-44 _____ is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claims 1-44 _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of References Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152
- ☒ Notice to Comply with Requirements for Sequence Disclosures

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide And/Or Amino Acid Sequence Disclosures.

It is noted that a proper sequence listing was submitted on 12/23/99 for this application. However, the CRF diskette appears to have been lost in the process of entry. Consequently, in order to be responsive to this restriction requirement, applicant is required to comply with sequence rules by submitting another CRF diskette and a statement saying that said disk is identical to the paper copy submitted on 12/23/99. The examiner apologizes for any inconvenience.

2. Restriction to one of the following inventions is required under 35 CFR121:

Group I, claims 1-7 and 26, drawn to a nucleic acid which codes for the alpha chain of a human TCR and a composition thereof, a vector, and a host cell, classified in class 435, subclasses 320.1 and 252.3, class 536, subclass 23.1, and class 514, subclass 44,

Group II, claims 8-9, 18-22, and 26, drawn to an isolated polypeptide and a composition thereof, classified in class 530, subclass 395 and Class 514, subclass 12,

Group III, claims 10-17, and 26, drawn to a nucleic acid which codes for the beta chain of a human TCR and a composition thereof, a vector, and a host cell, classified in class 435, subclasses 320.1 and 252.3, class 536, subclass 23.1, and class 514, subclass 44,

Group IV, claims 23-24, drawn to an antibody, classified in class 530, subclasses 387.1, and 387.9,

Group V, claim 25, drawn to a T cell, classified in Class 435, subclass 372.3,

Group VI, claims 27-29, drawn to a method for the production of an agent for the diagnosis of tumour disease, classified in class 435, subclasses 6 and 7.2,

Group VII, claims 30-36, drawn to a method for the production of an agent for the prevention or therapy of tumour disease, classified in class 435, subclasses 6 and 7.2,

Group VIII, claims 37-41, drawn to a method for the isolation of T cells, classified in class 435, subclass 372.3,

Group IX, claim 42, drawn to a transgenic animal, classified in class 800, subclass 13,

Group X, claims 43-44, drawn to a method for the identification of peptide

ligands of a T cell receptor, classified in class 436, subclasses 6 and 7.24.

3. Inventions IV and VIII are related as a product and a processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case, the antibody can be used for other process such as in a method of complement mediated lysis of T cells.

4. Inventions V and X are related as a product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case, the T cell can be used in a method to study apoptosis.

5. Inventions I/III and VI/VII are related as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05(h)). In the instant case, the nucleic acid encompassed by Groups I/III can be used in a process of producing DNA vaccines.

6. Inventions I/II/III/IV/V/IX are different products. Inventions IX and V and I/II/III/IV encompass a transgenic animal, a cell and subcellular biochemical molecules, respectively, and are different structural entities. Inventions I/III and IV/II encompass nucleic acids and amino acids respectively which have different biochemical characteristics, structure and functions. Inventions I and III encompass nucleic acid sequences that encode different proteins which have different biochemical characteristics, structure and functions. Inventions IV and II encompass antibodies and proteins, respectively, and are distinct because their structures and modes of action are different. In view of their unique characteristics and different searches for examination purposes, Inventions I/II/III/IV/V/IX are patentably distinct.

7. Inventions VI/VII/VIII/X are different methods. These inventions require different process steps and endpoints. Invention VI is drawn to a method for the production of an agent for the diagnosis of tumour disease, Invention VII is drawn to a method for the production of an agent for the prevention or therapy of tumour disease, Invention VIII is drawn to a method for the isolation of T cells, while Invention X is drawn to a

method for identification of peptide ligands of a T cell receptor. Accordingly said methods of these inventions have distinct process steps and endpoints and are therefore, patentably distinct.

8. Because the inventions are distinct for the reasons given above and the search required for each Group is not required for the other and because each Invention has acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

9. If Group VI or VII is elected, the applicant is further required under 35 U.S.C. 121 to elect a pharmaceutical composition that contains **one of the following active components**:

- A) a nucleic acid as recited in Claims 1-4 or 10-4,
- B) a polypeptide as recited in Claims 8, 9, or 18-23,
- C) a ligand against the polypeptide recited in Claims 8, 9, or 18-23,
- D) a antibody as recited in Claim 23 or 24, or
- E) a cell as recited in claims 6, 7, 16, 17 or 25.

10. Applicant is required, in response to this action, to elect a specific embodiment to which the claims shall be restricted if no generic claim is finally held to be allowable. The response must also identify the claims readable on the elected embodiment, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

11. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional embodiments which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected embodiment. MPEP § 809.02(a).

12. The following claim(s) are generic: claims 27-29 and 30-36.

13. The species are distinct each from the other for the following reasons:

A) The recited nucleic acid, polypeptide, peptide ligand, antibody and cell have different biochemical characteristics, structure and functions.

14. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

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15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. Or a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-305-3704. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

Amy DeCloux, Ph.D.
Patent Examiner
Group 1640, Technology Center 1600
March 17, 2000

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ / 1644